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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 5/30	A1	(11) International Publication Number: WO 96/15821
		(43) International Publication Date: 30 May 1996 (30.05.96)

(21) International Application Number: PCT/GB95/02649

(22) International Filing Date: 13 November 1995 (13.11.95)

(30) Priority Data:
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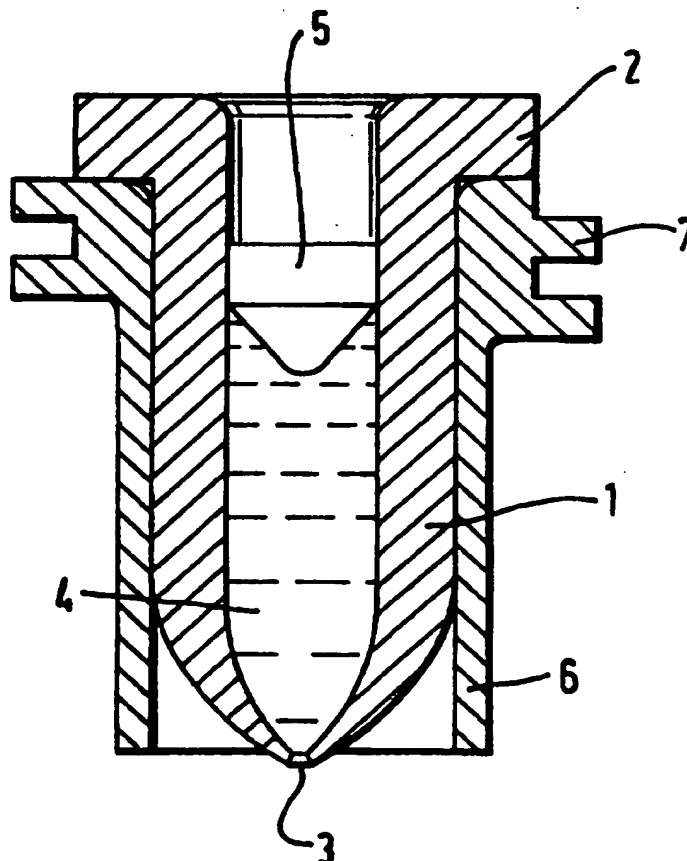
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Road, Sevenoaks, Kent TN13 1XR (GB).(81) Designated States: AL, AM, AT, AU, BB, BG, BR, BY, CA,
CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP,
KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG,
MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE,
SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, European
patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU,
MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE,
LS, MW, SD, SZ, UG).**Published***With international search report.**Before the expiration of the time limit for amending the
claims and to be republished in the event of the receipt of
amendments.*

(54) Title: MEDICAL GLASS CONTAINER SUITABLE FOR USE IN NEEDLELESS INJECTORS

(57) Abstract

A cylindrical medical glass container (1) suitable for use in needleless injectors contains a liquid (4) and a piston (5) in contact with the liquid. By acting on the piston (5) with a ram, liquid (4) is highly pressurised and dispensed rapidly through a hole (3) in a container (1). To prevent the glass container from breaking during pressurisation, a comprehensive sleeve (6) is fitted to the outside of the container (1).



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MEDICAL GLASS CONTAINER SUITABLE FOR USE IN NEEDLELESS INJECTORS

The invention relates to glass containers, particularly those subjected to high pressures.

International Specification WO 95/03844 discloses a needleless injector for delivering a liquid medicament into the skin. During the injection, very high pressures of short duration are generated. A preferred embodiment of that invention requires a liquid medicament to be stored in the dispenser in a glass container, preferably a cylindrical glass container, which also serves as the pressure vessel. In order to withstand these high pressures, the container may be provided with thick walls. However, these make it more difficult and costly to make. These size and cost disadvantages partly offset the potential benefits of needleless injectors compared with conventional hypodermic syringes. It is an object of a preferred embodiment of the present invention to provide a glass container which can be used in such a needleless injector, without it having to be provided with such thick walls.

The invention employs the principle that glass is able to withstand higher forces if the surfaces are maintained in a state of compressive stress. The accepted theories on glass fracture propose that breakage occurs through the rapid growth of microcracks on the glass surface when the glass is stressed, in addition to fractures originating from gross surface defects. By holding the surfaces in compressive stress, this stress must be overcome before crack growth can occur.

According to the present invention there is provided a container adapted to withstand a high internal pressure, comprising a hollow glass body and compression means for exerting a compressive force on the hollow glass body.

In one embodiment thereof the compression means is a tight fitting sleeve assembled onto the capsule body so as to exert a compressive force on a preferably cylindrical

wall thereof.

It has been found that a borosilicate glass cylinder having a bore of 5mm diameter and a wall thickness of 2.19mm will sometimes break when subjected to internal pressures of 80 bars and transient pressures of 4000 bars. Furthermore, the cylinders are unable to withstand more than two applications of such pressures. A polycarbonate sleeve having a nominal interference fit of 0.05mm enables the cylinders to withstand at least 20 applications of such pressures without damage.

An embodiment of the invention is shown in the single figure of drawing, which is a diagrammatic longitudinal section.

Figure 1 shows a glass needleless injection capsule 1 having a main body portion defined by a wall which is cylindrical both internally and externally, a flange 2 at one end thereof, and a tapered portion at the other end terminating in a discharge orifice 3. The capsule 1 contains injectate 4 and a free, slidable piston 5. A sleeve 6 is an interference fit onto the cylindrical wall of the capsule 1. A thread 7 on the sleeve 6 enables the assembly to be screwed into and retained by an injector actuator (not shown). There are many alternative methods of securing the assembly to the actuator, such as snap fitting, or ultrasonic welding, adhesives, or metal clips, to name a few examples.

In use, the discharge orifice 3 is placed on the subject's skin, and the free piston 5 is struck by the ram of the actuator. This blow is transferred to the injectate 4 causing a rapid rise in pressure. This causes a corresponding tensile stress in the walls of the capsule 1, tending to burst it. This is prevented by the compressive stress induced by the tight-fitting sleeve 6 which partly or fully resists the tensile stress resulting from the hydraulic impact.

Thus it may be seen that the invention prevents the breakage of glass capsules when subjected to high pressure.

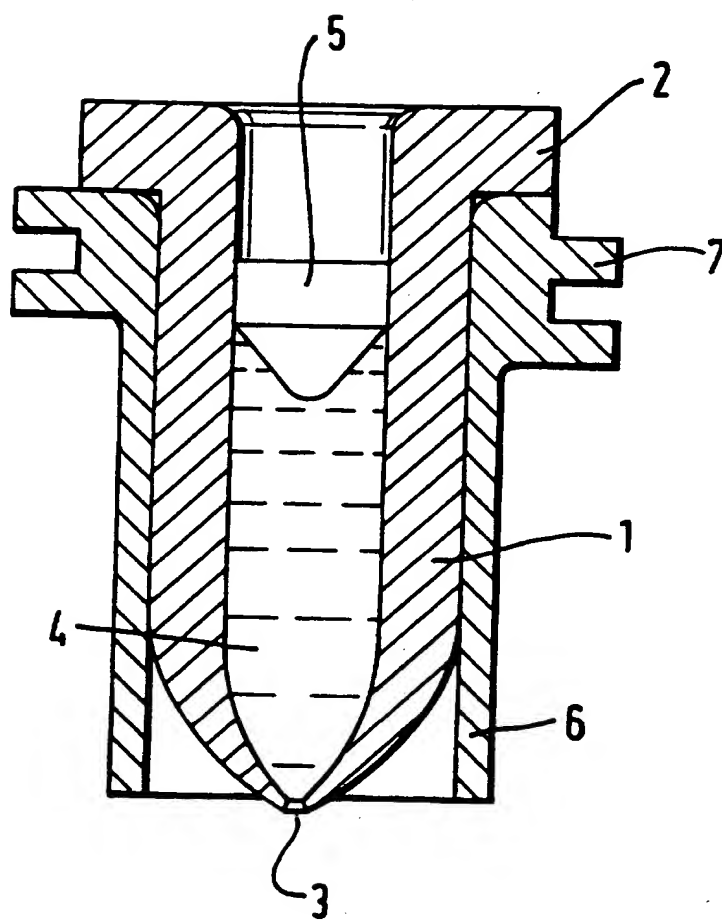
It also protects the glass surface from damage during storage.

The sleeve 6 is preferably made from a transparent plastic, such as a polycarbonate, polyethertetrapthalate, polystyrene, or cellulose ester (e.g. cellulose acetate-propionate), which enables the contents to be examined. The strength of the glass may be further improved by ion stuffing, thermal pre-stressing, or etching, and the present specification allows for all combinations of materials and processes which will achieve the object of the invention.

CLAIMS:

1. A glass container adapted to withstand a high internal pressure, comprising a hollow glass body and compression means for exerting a compressive force on the hollow glass body.
2. A container according to claim 1, wherein the hollow glass body is generally cylindrical over at least a portion thereof.
3. A container according to claim 1, adapted for use as a capsule in a needleless injector, comprising a main body portion defined by an internally cylindrical wall, has a flange at one end thereof, and a tapered portion at the other end terminating in a discharge orifice.
4. A container according to claim 3, wherein the wall of the main body portion is also externally cylindrical.
5. A glass container according to any preceding claim, wherein the compression means is a sleeve which fits tightly around the hollow glass body.
6. A container according to claim 5, wherein the sleeve is of a plastics material.
7. A container according to claim 6, wherein the plastics material is transparent.
8. A container according to claim 7, wherein the plastics material is selected from the group consisting of polycarbonates, polyethertetraphthalates, polystyrenes and cellulose esters.
9. A container according to claim 8, wherein the plastics material is cellulose acetate-propionate.

1 / 1



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 95/02649

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M5/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,3 650 084 (MORELAND) 21 March 1972 see column 3, line 60 - column 4, line 8 see column 4, line 62 - line 64 see figures 8,14	1-5,7,8
X	US,A,3 688 765 (GASAWAY) 5 September 1972 see column 3, line 54 - line 65 see column 4, line 1 - line 4	1-5
X	US,A,3 782 380 (VAN DER GAAST) 1 January 1974 see column 2, line 47 - line 49 see column 2, line 59 - line 60 see column 4, line 7 - line 15	1,2,5
A		3,4
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- * Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- * &* document member of the same patent family

Date of the actual completion of the international search

2 April 1996

Date of mailing of the international search report

15.04.96

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INTERNATIONAL SEARCH REPORT

Int'l Application No
PCT/GB 95/02649

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>EP,A,0 584 531 (MEDRAD INC.) 2 March 1994 see column 9, line 23 - line 35 see figures 9,10 -----</p>	6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 95/02649

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-3650084	21-03-72	US-A- 3540444	17-11-70
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US-A-3782380	01-01-74	NONE	
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		CA-A- 2097848	18-02-94
		JP-A- 6154322	03-06-94

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